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Speaker Packet for

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Label Comprehension Session

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Rx-to-OTC Switch A Research Driven Process

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Good Morning (or afternoon), I am Susan Shellabarger and I am the Senior Director of Business Development for OTC Products for Hill Top Research. I am very pleased that the FDA is holding this very important meeting on OTC Drug products and I want to thank the FDA for allowing me to share my comments.

I am representing myself and am not receiving any financial payment for presenting my views.

Label Comprehension & Actual Use Studies

- Proven to be useful tools that meet the unique scientific and regulatory issues that characterize the Rx-to-OTC Switch process
- Market Research or Consumer Research is very scientific in its design, implementation and management/interpretation of data.
- "Naturalistic" or "All Comers" study approaches for subject enrollment are likely better representations of the user population than what is routinely experienced in Rx Phase II/III trials which have extensive inclusion/exclusion criteria that can bias the study population

Over the past few years many company sponsors have used studies that have become unique to the Rx-to-OTC switch process. These studies fall into two categories: Label Comprehension studies and Actual Use (or All Comer or Naturalistic) studies. Label comprehension studies have proven to be useful tools for evaluating the general consumers' ability to read and understand a product label, as well as gaining insight into the consumers' behavioral intent regarding the use of a new product. Actual Use studies strive to reach the next level of consumers' actual behavior regarding the purchase and use of the product without any influence from an healthcare professional.

Many clinical scientists categorize these studies as Market Research or Consumer Research and therefore assume they are not scientifically valid. I believe just the opposite is true. These studies are very scientific in their design, implementation and management and analysis of the data and have become an essential basis for switch today.

In fact, the "all comers" approach to subject recruiting provides a very representative sample of the user population - much more so than what is routinely practiced in Rx Phase II and III clinical trials where there are extensive inclusion/exclusion criteria than can bias the study population.

Example: Heartburn Labels

- Earliest OTC labels used bar graphs to show efficacy information
- A research project was undertaken to investigate consumer comprehension of such efficacy data under four experimental conditions (Consumer Comprehension of Efficacy Data In Four Experimental Over-The-Counter Label Conditions, *Drug Information Journal*, Volume 31, No. 3, 1997)

Control Label:	No efficacy information
Efficacy Data:	Text Format
Efficacy Data:	Bar Graph Format
Efficacy Data:	Enhanced Bar Graph Format

I would like to share an example of a label decision based upon subjective information.

The very first H2 blockers introduced to the OTC market had efficacy data provided in the form of bar graphs. While most of us in this room have the education necessary to interpret bar graph information, my supposition was that this would not be the case for the general population.

Consequently, we designed a study to investigate consumer comprehension of such H2 blocker heartburn efficacy data under four different experimental label conditions. Copies of this paper which was published in the *Drug Information Journal* have been included in my presentation packet.

We had general population consumers look at four different labels. The first was a control label that contained no efficacy information at all. The second label provided efficacy data in text format. The third label used a bar graph format and the fourth label used a bar graph that was enhanced with text data.

Conclusions

- The Rx-to-OTC Switch research process should be considered on a case-by-case basis
- Label Comprehension and Actual Use studies have proven to be useful tools that meet the unique scientific and regulatory challenges that characterize the Rx-to-OTC process
- Decisions about labeling should be driven by data obtained through well designed and implemented studies - not through untested subjective views

I would like to conclude my remarks by restating three points:

1. Rx-to-OTC switches are strategically important not only for the manufacturers, but also for the general public's health. The Rx-to-OTC switch research process has been validated, but still should be considered on a case-by-case basis.
2. Label Comprehension and Actual Use studies, when well designed and implemented are scientifically valid and have proven to be useful tools in the evaluation of the Rx-to-OTC switch process.
3. OTC product labeling, much of the time acts as the "learned intermediary" for consumers. Therefore, decisions about product labeling should be driven by data obtained through well designed and implemented studies - not through untested, subjective views.

Thank you very much for allowing me the time on today's docket to present my views.